

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75256_S6

CHEMISTRY REVIEW(S)

ANDA 75-256/S-006

NAME AND ADDRESS OF APPLICANT:

Duramed Pharmaceuticals, Inc.
5040 Lester Road
Cincinnati, OH 45213

PURPOSE OF AMENDMENT/SUPPLEMENT

To release one batch which slightly exceeded the established granulation drying parameter.

DATE(S) OF SUBMISSION(S)

March 21, 2001

PHARMACOLOGICAL CATEGORY

Oral Contraceptive

TRADE NAME

None used

NONPROPRIETARY NAME

Desogesterel and Ethinyl Estradiol

DOSAGE FORM

Tablets

POTENCY

0.15 mg/0.03 mg

RX OR OTC

Rx

REMARKS AND CONCLUSION

Approved.

RECALLS

N/A

Reviewer

Mujahid L. Shaikh

Date Completed

7-23-01

cc: ANDA # 75-256

Division File

Field Copy

Endorsements:

HFD-625/M.Shaikh/7/23/01

HFD-625/M.Smela/7/24/01

ISI

7/25/01

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